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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,899	11/14/2003	Thomas D. Klingner	400491	9478

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EXAMINER	
WEBB, GREGORY E	

ART UNIT	PAPER NUMBER
1751	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,899	KLINGNER, THOMAS D.	
	Examiner	Art Unit	
	Gregory E. Webb	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1103*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (c) he has abandoned the invention.
>
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (f) he did not himself invent the subject matter sought to be patented.

> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tipton (US5632727).

Concerning the percutaneous, Tipton teaches the following:

In a preferred version, the film dressing has a two-layered asymmetric pore structure composed of a core portion and a skin portion. The skin portion has pores with significantly smaller diameters than that of the pores in the core portion. The skin portion can be formed on top of the core portion with the core portion in contact with the tissue, or the skin portion or layer may be under the core portion and in contact with the tissue. FIG. 2 shows a cross-sectional view of a microporous film dressing (10) formed on skin tissue (20) showing a two-layered pore structure with a skin portion (12) formed on top of the core portion (14) in contact with the skin tissue (20). As shown, the pores (16) of the skin portion (12) are smaller diameter than the pores (18) of the core portion (14). Alternatively, the film dressing can have a homogeneous pore structure with pores evenly distributed throughout the film dressing.(see col. 7)

Concerning the absorbtion and the percutaneous absorption, Tipton teaches the following:

21. The microporous film dressing of claim 18, wherein the biodegradable film further comprises an agent capable of altering percutaneous absorption of the biologically active agent.(see claim 21)

Concerning the skin protection, Tipton teaches the following:

12. The microporous film dressing of claim 1, wherein the film dressing is in the form of a bandage, suture, surgical barrier, wound dressing, or combination thereof.(see claim 12)

Concerning the molecular weight, Tipton teaches the following:

The thermoplastic polymer is combined with a suitable organic solvent to form a dispersion or solution. The solubility or miscibility of a polymer in a particular solvent will vary according to factors such as crystallinity, hydrophilicity, capacity for hydrogen-bonding and molecular weight of the polymer. Consequently, the molecular weight and the concentration of the polymer in the solvent are adjusted to achieve desired miscibility. Highly preferred thermoplastic polymers are those which have solubility parameters which include a low degree of crystallization, a low degree of hydrogen-bonding, low solubility in water, and a high solubility in organic solvents. In addition, the molecular weight and concentration of the polymer in the solvent can be adjusted to achieve the desired viscosity. The liquid composition preferably has a viscosity which effectively provides for aerosolization of the composition while maintaining sufficient adhesion and cohesive strength of the film dressing. A viscosity that effectively provides for aerosolization is a viscosity which provides the liquid composition with flow properties and surface tension sufficient to allow for formation of

small droplets in an aerosol. The viscosity can also be such that the evaporation of the solvent is not rapid enough to prevent coalescence of the aerosol drops on the surface of the tissue in the formation of the film dressing. Suitable solution viscosities include about 0.1 to 2000 cps, preferably about 1 to 100 cps, more preferably about 1 to 50 cps.(see col. 5, lines 39-65)

Concerning the barrier, Tipton teaches the following:

7. The microporous film dressing of claim 1, wherein the biodegradable film is capable of providing a mechanical barrier, a microbial barrier, or a combination thereof, on a tissue.(see claim 7)

Concerning the solvent, Tipton teaches the following:

A mixture of solvents can be used to increase the coagulation rate of polymers which exhibit a slow coagulation or setting rate. For example, the polymer can be combined with a coagulant-promoting solvent system composed of a mixture of a good solvent and a poorer solvent or a non-solvent for the polymer component. It is preferred that the solvent mixture contain an effective amount of the two solvents such that the polymer will remain soluble in the mixture but coagulate upon dissipation or diffusion of the solvents into surrounding tissue fluids at the tissue site.(see cols. 6-7)

Concerning the propylene glycol, Tipton teaches the following:

22. The microporous film dressing of claim 21, wherein the absorption altering agent is selected from the group consisting of propylene glycol,

glycerol, urea, diethyl sebecate, sodium lauryl sulfate, sodium laurye sulfate, sorbitan ethoxylates, oleic acid, pyrrolidone carboxylate esters, N-methyl pyrrolidone, N,N-diethyl-m-toluamide, dimethyl sulfoxide, alkyl methyl sulfoxides, and mixtures thereof.(see claim 22)

In example 1, Tipton teaches the use of various components including pH adjusting agents such as citric acid and sodium carbonate.

Concerning the UV blocker, Tipton teaches various dyes which would inherently absorb UV light (see col. 11, lines 1-20).

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tipton (US5725491).

Concerning the percutaneous, Tipton teaches the following:

In a preferred version, the film dressing has a two-layered asymmetric pore structure composed of a core portion and a skin portion. The skin portion has pores with significantly smaller diameters than that of the pores in the core portion. The skin portion can be formed on top of the core portion with the core portion in contact with the tissue, or the skin portion or layer may be under the core portion and in contact with the tissue. Alternatively, the film dressing can have a homogeneous pore structure with pores evenly distributed throughout the film dressing.(par#35)

Concerning the absorbtion and the percutaneous absorption, Tipton teaches the following:

Additives can also be incorporated into the liquid composition to effect

both drug release and mechanical properties. Plasticizers increase the flexibility of the microporous film dressing. Agents can be added to modify the release of drugs and/or to enhance percutaneous absorption of the drug after release.(par#18)

Concerning the barrier layer, Tipton teaches the following:

Most currently available topical therapeutic formulations used with dressings are inefficient. This inefficiency results because of loss of the therapeutic agents through perspiration and mechanical action, inability of the agent to penetrate skin and mucous membranes, and crystallization or precipitation of the agents at the tissue site. Some topical therapeutic formulations are incorporated into the materials forming the dressings to be applied as patches, preformed sheets or by spray. More typically, wound coverings or dressings are used with ointments of a topical antibiotic and/or antifungal formulations. Whether used with or without dressings, topical formulations in the form of creams, ointments or liquids are difficult to apply and maintain at the injury site. They are rapidly removed by mechanical action and/or body fluid dissolution. If used in combination with a dressing, therapeutic formulations have several other drawbacks including lack of biodegradability, damage or irritation to the skin during removal of the dressing, covalent bonding or other interaction of the therapeutic agent and the dressing, inability to use a wide variety of therapeutic agents,

and inadequate adhesion of the dressing.(par#10)

Concerning the molecular weight, Tipton teaches the following:

The thermoplastic polymer is combined with a suitable organic solvent to form a dispersion or solution. The solubility or miscibility of a polymer in a particular solvent will vary according to factors such as crystallinity, hydrophilicity, capacity for hydrogen-bonding and molecular weight of the polymer. Consequently, the molecular weight and the concentration of the polymer in the solvent are adjusted to achieve desired miscibility. Highly preferred thermoplastic polymers are those which have solubility parameters which include a low degree of crystallization, a low degree of hydrogen-bonding, low solubility in water, and a high solubility in organic solvents. In addition, the molecular weight and concentration of the polymer in the solvent can be adjusted to achieve the desired viscosity. The liquid composition preferably has a viscosity which effectively provides for aerosolization of the composition while maintaining sufficient adhesion and cohesive strength of the film dressing. A viscosity that effectively provides for aerosolization is a viscosity which provides the liquid composition with flow properties and surface tension sufficient to allow for formation of small droplets in an aerosol. The viscosity can also be such that the evaporation of the solvent is not rapid enough to prevent coalescence of the aerosol drops on the surface of the tissue in the formation of the

film dressing. Suitable solution viscosities include about 0.1 to 2000 cps, preferably about 1 to 100 cps, more preferably about 1 to 50 cps.(par#27)

Concerning the barrier, Tipton teaches the following:

To provide an effective microporous film, it is preferred that the diameter of the pores be about 3-500 microns, more preferably about 3-200 microns, and even more preferably about 3-100 microns, and most preferably 3-50 microns. It is further preferred that the matrix has a porosity of about 5-95%, preferably about 25-85% in order to provide preferred water diffusivity, preferred exchange of nutrients and oxygen, preferred structural integrity including cohesive strength, and an preferred barrier to microorganisms.(par#40)

Concerning the solvent, Tipton teaches the following:

A mixture of solvents can be used to increase the coagulation rate of polymers which exhibit a slow coagulation or setting rate. For example, the polymer can be combined with a coagulant-promoting solvent system composed of a mixture of a good solvent and a poorer solvent or a non-solvent for the polymer component. It is preferred that the solvent mixture contain an effective amount of the two solvents such that the polymer will remain soluble in the mixture but coagulate upon dissipation or diffusion of the solvents into surrounding tissue fluids at the tissue site.(par#33)

Concerning the propylene glycol, Tipton teaches the following:

Examples of suitable compounds which can be added to increase percutaneous absorption of biologically active agents include propylene glycol, glycerol, urea, diethyl sebecate, sodium lauryl sulfate, sodium laurye sulfate, sorbitan ethoxylates, oleic acid, pyrrolidone carboxylate esters, N-methyl pyrrolidone, N,N-diethyl-m-toluamide, dimethyl sulfoxide, alkyl methyl sulfoxides, and mixtures thereof.(see col. 10, lines 52-58)

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Peck (US5703104).

Concerning the percutaneous, absorbtion, percutaneous absorption and the toxic chemical, Peck teaches the following:

In a third embodiment, the present invention relates to a method for decreasing the percutaneous absorption of toxic chemicals through the skin of a mammal which comprises applying to the stratum corneum of the skin of a mammal in need thereof a compound having one of Formulae I-IV in an amount effective to decrease the percutaneous absorption of toxic chemicals.(see col. 2, lines 17-23)

Concerning the molecular weight and the propylene glycol, Peck teaches the following:

Lotions may be conveniently prepared by dissolving the active ingredient, in a suitable high molecular weight alcohol such as propylene glycol or polyethylene glycol.(see col. 7, lines 8-15)

Concerning the barrier and the prevents absorption, Peck teaches the following:

Compounds, topical compositions and methods useful for preventing the penetration of toxic chemicals through the skin of a mammal are disclosed. The compounds of the invention provide an enhanced barrier for the skin of a mammal to further inhibit or decrease the passage of bioactive agents through the skin of a mammal either from the outside environment into the systems of said mammal or from the mammal into the outside environment.(see abstract)

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tipton (US5792469).

Concerning the percutaneous, Tipton teaches the following:

In a preferred version, the film dressing has a two-layered asymmetric pore structure composed of a core portion and a skin portion. The skin portion has pores with significantly smaller diameters than that of the pores in the core portion. The skin portion can be formed on top of the core portion with the core portion in contact with the tissue, or the skin portion or layer may be under the core portion and in contact with the tissue. Alternatively, the film dressing can have a homogeneous pore structure with pores evenly distributed throughout the film dressing.(see col. 7, lines 1-12)

Concerning the absorbtion and the percutaneous absorption, Tipton teaches the following:

9. The composition of claim 1, comprising a biologically-active agent and an agent to alter percutaneous absorption of the biologically-active agent.(see claim 9)

Concerning the dressing, Tipton teaches the following:

> Most currently available topical therapeutic formulations used with dressings are inefficient. This inefficiency results because of loss of the therapeutic agents through perspiration and mechanical action, inability of the agent to penetrate skin and mucous membranes, and crystallization or precipitation of the agents at the tissue site. Some topical therapeutic formulations are incorporated into the materials forming the dressings to be applied as patches, preformed sheets, or by spray. More typically, wound coverings or dressings are used with ointments of a topical antibiotic and/or antifungal formulations. Whether used with or without dressings, topical formulations in the form of creams, ointments or liquids are difficult to apply and maintain at the injury site. They are rapidly removed by mechanical action and/or body fluid dissolution. If used in combination with a dressing, therapeutic formulations have several other drawbacks including lack of biodegradability, damage or irritation to the skin during removal of the dressing, covalent bonding or other interaction of the therapeutic agent and the dressing, inability to use a wide variety of therapeutic agents, and inadequate adhesion of the dressing.(see col. 1, lines 30-50)

Concerning the molecular weight, Tipton teaches the following:

> The thermoplastic polymer is combined with a suitable organic solvent to form a dispersion or solution. The solubility or miscibility of a polymer in a particular solvent will vary according to factors such as

crystallinity, hydrophilicity, capacity for hydrogen-bonding and molecular weight of the polymer. Consequently, the molecular weight and the concentration of the polymer in the solvent are adjusted to achieve desired miscibility. Highly preferred thermoplastic polymers are those which have solubility parameters which include a low degree of crystallization, a low degree of hydrogen-bonding, low solubility in water, and a high solubility in organic solvents. In addition, the molecular weight and concentration of the polymer in the solvent can be adjusted to achieve the desired viscosity. The liquid composition preferably has a viscosity which effectively provides for aerosolization of the composition while maintaining sufficient adhesion and cohesive strength of the film dressing. A viscosity that effectively provides for aerosolization is a viscosity which provides the liquid composition with flow properties and surface tension sufficient to allow for formation of small droplets in an aerosol. The viscosity can also be such that the evaporation of the solvent is not rapid enough to prevent coalescence of the aerosol drops on the surface of the tissue in the formation of the film dressing. Suitable solution viscosities include about 0.1 to 2000 cps, preferably about 1 to 100 cps, more preferably about 1 to 50 cps.(see col. 5)

Concerning the barrier, Tipton teaches the following:

6. The composition of claim 1, wherein the film is a flexible, mechanical and microbial barrier dressing on the tissue.(see claim 6)

Concerning the solvent, Tipton teaches the following:

> A mixture of solvents can be used to increase the coagulation rate of polymers which exhibit a slow coagulation or setting rate. For example, the polymer can be combined with a coagulant-promoting solvent system composed of a mixture of a good solvent and a poorer solvent or a non-solvent for the polymer component. It is preferred that the solvent mixture contain an effective amount of the two solvents such that the polymer will remain soluble in the mixture but coagulate upon dissipation or diffusion of the solvents into surrounding tissue fluids at the tissue site.(see col. 6, lines 49-59)

Concerning the soybean oil, Tipton teaches the following:

> 10. The composition of claim 8, wherein the modifying agent is selected from the group consisting of phthalic esters, benzylphthalates, glycol benzoates, trimellitates, adipates, azelates, sebacates, esters of aliphatic and aromatic di- and tricarboxylic acids, organic phosphates, sesame oil, soybean oil, and combinations thereof.(see claim 10)

Concerning the propylene glycol, Tipton teaches the following:

> 11. The composition of claim 9, wherein the absorption altering agent is selected from the group consisting of propylene glycol, glycerol, urea, diethyl sebecate sodium, lauryl sulfate, sodium lauryl sulfate, sorbitan ethoxylates, oleic acid, pyrrolidone carboxylate esters, N-methylpyrrolidone, N,N-diethyl-m-tolumide, dimethyl sulfoxide, alkyl

methyl sulfoxides, and combinations thereof.(see claim 11)

Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Peck (US6086905).

Concerning the percutaneous and the barrier, Peck teaches the following:

The above penetration prevention agents may be formulated into topical compositions which, when applied to the skin of a mammal, e.g., a human, will function as barriers to the passage of bioactive compounds and agents through the skin in either or both directions. That is, the barrier may prevent the passage of toxic chemicals from the environment through the skin into the bloodstream or underlying tissues and/or organs of the mammal. This utility is especially desirable to prevent certain individuals from being exposed to toxic chemicals; e.g., farmers dealing with pesticides, workers cleaning up toxic waste spills, soldiers exposed to chemical weapons, etc. The barrier may also function to prevent allergic reactions to skin products such as cosmetics, sunburn preparations, etc., wherein it is desired to maintain the skin product ingredients on the surface of the skin. Additionally, the barrier may function to maintain drugs utilized to treat skin conditions on the skin surface.(see col. 3)

Concerning the absorbtion and the percutaneous absorption, Peck teaches the following:

1. A method for decreasing the percutaneous absorption of toxic chemicals through the skin of a mammal in need of said decreasing which comprises

applying to the stratum corneum of the skin of said mammal an effective amount to decrease the percutaneous absorption of toxic chemicals of a compound having the formula:

##STR4##

wherein W.sub.1, W.sub.2 and W.sub.3 are each divalent oxygen, n is 2 and R is a straight chain alkyl radical containing 6 to 20 carbon atoms;(see claim 1)

Concerning the prevents absorption, Peck teaches the following:

It is also an object to provide topical compositions for providing a barrier for the skin of a mammal to prevent the passage of bioactive agents in either direction through the skin.(see col. 1, lines 45-50)

Concerning the solvent, Peck teaches the following:

5 gm (0.0574 mole) 2-oxazolidone was partially dissolved with heating in 100 ml toluene. 24 ml (0.172 mole) triethylamine was added to the stirred mixture. Via dropping funnel 17.26 ml (0.0746 mole) lauroyl chloride was added. This mixture was then stirred 0.5 hour at room temperature. The reaction mixture was then filtered and the filtrate concentrated. The concentrate was dissolved in dichloromethane and this solution shaken with saturated aqueous sodium bicarbonate. The organic phase was dried over magnesium sulfate, filtered, concentrated and placed under high vacuum. Upon complete drying, the residue was triturated with petroleum ether and the solvent decanted off. The residue was purified by flash chromatography, employing ethyl acetate/petroleum ether as the eluant. The

yield was 8.45 gm (55%) of a white solid with a melting point of

63-65.degree. C.(see example 1)

Concerning the toxic, Peck teaches the following:

wherein when the skin of said mammal is exposed to said toxic chemicals,

the penetration of said toxic chemicals through the skin is decreased.(see claim 1)

Concerning the propylene glycol, Peck teaches the following:

Dosage forms for topical application may include solution nasal sprays,

lotions, ointments, creams, gels, suppositories, sprays, aerosols and the

like. Typical inert carriers which make up the foregoing dosage forms

include water, acetone, isopropyl alcohol, freon, ethyl alcohol,

polyvinylpyrrolidone, propylene glycol, fragrances, gel-producing

materials, mineral oil, stearyl alcohol, stearic acid, spermaceti,

sorbitan monooleate, "Polysorbates", sorbitol, methyl cellulose, etc.(see col. 4, lines 3-11)

Claims 14-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Klingner (US5140986).

Concerning the percutaneous, Klingner teaches the following:

Methods previously used to assess skin exposure to toxic chemicals in the

workplace include visual examination of the skin for discoloration or

other visible effects, the use of an absorbent pad placed next to the skin

to collect contaminants during the workday, and testing of the skin by

wiping or washing it to remove and collect contaminant materials therefrom. Visible examination of the skin may not be effective in many cases where skin change does not occur until after a considerable length of time or after the cumulative effects of a number of periods of exposure. A major limitation of prior wiping and absorbent pad collection techniques is the requirement for laboratory analysis of the skin wipe or absorbent pad for contamination, which results in delayed reporting of results and increased costs.(see col. 1)

Concerning the absorbtion and the molecular weight, Klingner teaches the following:

Referring to FIG. 3, there is illustrated an alternative collection and detection pad 40, which is substantially the same as the pad 10, except that in this case the collection region is also impregnated with a chemical substance 42 over substantially the entire area thereof, as indicated in broken line, the substance 42 being selected to facilitate removal of the contaminant of interest from the dermal area 16. The chemical substance 42 may be a suitable solvent which is non-toxic and compatible with the human skin and which is a good solvent for the contaminant of interest. Preferably, the chemical substance 42 will also have a relatively high molecular weight, preferably above 400, to prevent absorption through the skin.(see col. 4, lines 55-65)

Concerning the solvent, Klingner teaches the following:

In modifications of EXAMPLE II, the solvent 20 may be another organic

solvent such as toluene, that is an effective solvent for the isocyanate but does not contain an acid or other chemical group that will react with the isocyanate.(see col. 6, lines 13-17)

Concerning the toxic, Klingner teaches the following:

The present invention relates to techniques for assessing skin exposure to contaminants, such as toxic chemicals or the like.(see col. 1, lines 5-10)

Concerning the decontamination, Klingner teaches the following:

Skin exposure constitutes an important route of entry into the human body for a large number of toxic chemicals. Circumstances may exist where absorption through the skin may equal or exceed the amount of chemical taken in through inhalation over a given period of time, such as an eighthour workday. Toxic contaminants may either affect the skin itself or have systemic toxicity, the extent of the effect depending upon the physical and chemical properties of the contaminant, the anatomical area of contact, the duration of contact and inter-personal variability, as well as environmental conditions. Various decontamination procedures have been adopted for certain workplace environments to remove contaminants from the skin, but it is first necessary to detect the presence of the contaminant on the skin to determine whether decontamination procedures are called for.(see col. 1, lines 10-30)

Concerning the propylene glycol and the polypropylene glycol, Klingner teaches the following:

In modifications of EXAMPLE I, the chemical substance 42 in the collection

region 11 may be other types of high molecular weight cosmetic grade material, such as polypropylene glycol or ethoxylated derivatives. The reagent 15 may incorporate a wide range of coupling reagents other than naphthol AS. Also, other buffers or nitrite salts such as potassium nitrite could be used, or solvents such as acidic methanol or acetone. Alternatively, other reagent systems, such as aromatic aldehydes or fluorescent reagents may be used for the detection of aromatic amines.(see cols. 5-6)

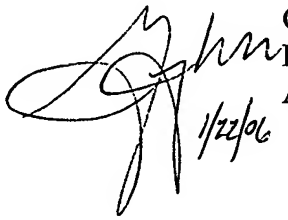
Conclusion

Although no claims have been indicated as allowable, it is suggested that the applicant more specifically define the chemicals used in the process of forming the barrier layer or removing toxic chemicals. Both process of forming a protective layer (i.e. a dressing) and cleaning a wound are well known. It is well known to clean a caustic wound with an acidic compound. It is also well known to form a barrier layer to the elements such as chapstick, etc. Thus the applicant should more clearly focus on similar claim limitations as those found in the allowed parent patent which is directed to the allowable composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory E. Webb whose telephone number is 571-272-1325. The examiner can normally be reached on 9:00-17:30 (m-f).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gregory E. Webb
Primary Examiner
Art Unit 1751

gew